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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

William Robert Carling et al.

Serial No.:

10/533,152

Case No.: T1567YP

Art Unit:

1624

Filed

April 27, 2005

Examiner:

Jeffrey H.

For

IMIDAZOPYRAZINONES AS GABA-A RECEPTOR

Murray

ANXIOLYTICS

Mail Stop: Patent Ext. Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Sir:

With reference to the Issue Notification mailed January 14, 2009, the Applicants respectfully request reconsideration of the Patent Term Adjustment for this application under 35 U.S.C. § 154(b).

This Request for Reconsideration of Patent Term Adjustment is being submitted within 2 months of the issuance of this application as US Patent 7,485,640 on February 3, 2009, and is accompanied by the fee set forth in 37 C.F.R. § 1.705(b)(1) and § 1.18(e). Any additional fees associated with this Request may be charged to Merck Deposit

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

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<u>REMARKS</u>

The Issue Notification mailed January 14, 2009, indicated that the total patent term adjustment calculated by the Patent Office for this application is <u>580</u> days. Applicants hereby respectfully request reconsideration of the patent term adjustment for this application. Specifically, Applicants believe that the total patent term adjustment should be <u>847</u> days.

In support of this request, Applicants submit the following statement of facts pursuant to 37 C.F.R. § 1.705(b).

- (i) Applicants agree with the determination by the Office that the USPTO delay under 37 C.F.R. § 1.703(a) is <u>584</u> days and that the Aplicant delay under 37 C.F.R. § 1.704(a) is <u>4</u> days. Applicants agree with the determination by the Office that the patent term adjustment under 37 C.F.R. § 1.702(a) as calculated under 37 C.F.R. § 1.703(a) and 37 C.F.R. § 1.704(a) is <u>580</u> days. The correct patent term adjustment calculated under 37 C.F.R. § 1.702(a) is <u>580</u> days.
- (ii) Applicants respectfully submit that the patent term adjustment under 37 C.F.R. § 1.702(b) as calculated under 37 C.F.R. § 1.703(b) is <u>282</u> days.

US Patent 7,485,640 granted from the subject application on February 3, 2009. This application was filed on April 27, 2005. Accordingly, the application should have issued within three years later, on April 27, 2008. However, the actual issue date was February 3, 2009. The difference between the date when the application should have issued to patent on April 27, 2008, and the date that the application actually issued to patent on February 3, 2009, is 282 days.

(iii) The adjustment sought under 37 C.F.R.§ 1.703(f) is the sum of the periods under § 1.703(a) (584 days) and § 1.702(b) (282 days), less the additional delays attributable to Applicant under 37 C.F.R. § 1.704(a) (4 days), less the days that the periods of delay under § 1.703(a) and § 1.703(b) overlap (15 days). Accordingly, Applicants respectfully request an adjustment of patent term under § 1.703(f) to indicate a total Patent Term Adjustment of 847 days.

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In support of Applicants' request for the adjustment under § 1.703(f) to include the sum of the periods under 1.702(a) and § 1.702(b), rather than the greater of these two periods, Applicants rely on the decision of the U.S. District Court for the District of Columbia in *Wyeth v. Dudas*, Civil Action No. 07-1492 (D.D.C. September 20, 2008). In that decision, the Court construed the meaning of the statutory provision regarding the limitations on extensions granted for delays under 35 U.S.C. § 154(b)(1)(A-C):

(A) In general. -- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). The court stated that "[t]he operative question under 35 U.S.C. § 154(b)(2)(A) is whether periods of delay attributable to grounds specified in paragraph (1) overlap." See Memorandum Opinion at p. 8. (internal quotations omitted). In the opinion of the district court, "[t]he only way that periods of time can "overlap" is if they occur on the same day." Id. The court thus rejected the Patent Office's view that any administrative delay under 35 U.S.C. § 154(b)(1)(A) ("A delays") overlaps with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B) ("B delay"). In the district court's view, the only A delays which overlap with the B delay are those which occur after the B period begins, which is when the Patent Office has failed to issue a patent within three years of an application's filing date, and not before. See Memorandum Opinion at p. 5-6, 9.

Applying the rule in Dudas to the present facts, the period for A delays ends on April 27, 2008, which is three years from the filing date of this application, April 27, 2005. The period for B delay begins on April 27, 2008, and ends on the date of issuance of the patent on February 3, 2009, a period of $\underline{282}$ days inclusive. Accordingly, the total patent term adjustment should be calculated from the sum of the A and B periods ($\underline{584} + \underline{282}$) days, less the delays due to applicant during the B period, $\underline{4}$ days, less the days that the A and B periods of delay overlap ($\underline{15}$ days) giving a total of $\underline{847}$ days.

Applicants note that the above-identified application is not subject to a terminal disclaimer.

In that the decision of the U.S. District Court for the District of Columbia in Wyeth v. Dudas is under appeal to the Court of Appeals for the Federal Circuit, Applicants respectfully request that any decision on this request for reconsideration of the patent term adjustment be held in abeyance until a final court decision in Wyeth v. Dudas is rendered.

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In summary, Applicants respectfully requests an adjustment of patent term under 37 C.F.R § 1.703(f) to indicate a total PTA of <u>847</u> days. Favorable consideration of this request is earnestly solicited.

Respectfully submitted,

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Date: March 5, 2009